REMARKS

Status of the Claims

Claims 36, 38-40, 42-44, 46-48, and 50-54 are currently pending in this application.

Claims 36, 38-40, 42-44, 46-48, and 50-54 stand rejected.

USPTO Policy on Compact Prosecution

According to the MPEP, "[i]t is essential that patent applicants obtain a prompt yet complete examination of their applications" (MPEP 2106 II). The MPEP also states that "the shortest path to the final disposition of an application is by finding the best references on the first search and carefully applying them" (MPEP 707.02). Moreover, the MPEP states that "[t]o bring the prosecution to as speedy conclusion as possible and at the same time to deal justly by both the applicant and the public, the invention as disclosed and claimed should be thoroughly searched in the first action and the references fully applied. . . . Switching . . . from one set of references to another by the examiner in rejecting in successive actions claims of substantially the same subject matter, will alike tend to defeat attaining the goal of reaching a clearly defined issue for an early termination." (MPEP 706.07). Moreover, the MPEP states that "it is to the interest of the applicants as a class as well as to that of the public that prosecution of an application be confined to as few actions as is consistent with a thorough consideration of its merits." (MPEP 706.07).

Applicants respectfully submit that the piecemeal examination of this case is unjustified and is inconsistent with the USPTO's policy on compact prosecution. This application has been pending for nearly 10 years and was, in fact, allowed by the Office several years ago, only to have the allowance withdrawn and a string on new rejections made, including rejections under §103 and §112, for which there can be no justification for not being raised earlier in the prosecution. Applicants are again confronted with yet another combination of references, despite the fact that the claims have not been amended. Now, the Examiner contends that the topical treatment of cellulite with perilla oil is rendered obvious by the observation that oral administration of perilla oil reduces visceral (not subcutaneous) fat, without the Examiner making even the most perfunctory effort at explaining why one skilled in the art would conclude that findings with respect to visceral adipose tissue are reasonably extensible to subcutaneous

adipose tissue. Applicants submit that the rejection is improper, for the reasons detailed below, and respectfully ask that the Examiner abide by the requirements of MPEP 707.02 in response to this paper to timely advance prosecution, and, if necessary, to permit Applicants to move the case to issuance through appeal to the Board.

Claim Rejections

§ 103 -- Obviousness

Claims 36, 38-40, 42-44, 46-48, and 50-54 stand rejected under 35 U.S.C. § 103 as unpatentable over Okuno et al, "Perilla Oil Prevents the Excessive Growth of Visceral Adipose Tissue in Rats by Down-Regulating Adipocyte Differentiation," *J. of Nutrition*, 1997 (Okuno), as evidenced by the "perilla oil" entry from the Wikipedia and U.S. Patent No. 5,705,170, in view of U.S. Patent No. 4,006,218 or U.S. Patent No. 4,537,776. Applicants traverse this rejection.

The Examiner relies on Okuno as teaching that rats fed a diet containing a high concentration of perilla oil have reduced adipose tissue growth. However, the Examiner ignores the fact that Okuno's findings are in relation to <u>visceral</u> fat, and not the <u>subcutaneous</u> fat implicated in cellulite. Indeed, Okuno's finding and conclusions are limited to "visceral adipose tissue in rats." [Abstract]. However, visceral adipose tissue is physiologically and biochemically quite distinct from the subcutaneous adipose tissue implicated in cellulite.

Any number of references illustrate the distinction between these two distinct tissue types. For example, the Examiner's attention is also drawn to Linder et al, "Differentially expressed genes in visceral or subcutaneous adipose tissue of obese men and women," *J. Lipid Res.*, Vol. 25, pp 148-154 (2004), which evidences the significant differences between visceral and subcutaneous adipose tissue. As explained in Linder, the "metabolic and endocrine functions of adipose tissue from various depots differ in a way that may explain the association of visceral but not subcutaneous fat with obesity-related cardiovascular and metabolic problems." Linder explains further that:

Regarding the metabolic function of fat, visceral adipose tissue is more sensitive to the stimulation of lipolysis by cathecolamines, whereas subcutaneous fat is more sensitive to the antilipolytic effects of insulin. Concerning endocrine function, visceral and

subcutaneous adipocytes have different capacities to produce hormones and enzymes. (Linder, p. 148)

Linder explains that the "mechanisms responsible for depot differences in adipose function are unknown" and suggests that it "is possible that fat cells in various regions have different origins and, because of this, express different genes," pointing to the following differences in mRNA expression:

Depot-related variation in mRNA expression has been shown for several genes, including leptin, TNF-α, angiotensinogen, PAI-1, and recently, carboxypeptidase E and thrombospondin-1. (Id.)

In view of the clear differences between visceral and subcutaneous adipose tissue, Applicants respectfully submit that Okuno's finding with respect to visceral adipose tissue would not have provided one skilled in the art with a reasonable expectation of successfully treating cellulite. Inasmuch as none of the other cited references disclose topical application of perilla oil to treat cellulite, they do not rectify the deficiencies of Okuno. Accordingly, Applicant respectfully submits that the rejection is improperly based on hindsight, as one skilled in the art would not have been motivated with a reasonable expectation of success to topically apply perilla oil to treat cellulite.

Having distinguished the independent claim from the art of record, Applicant submit that the claims dependent therefrom are patentable for at least the same reason. However, Applicants reserve the right to separately address the patentability of the dependent claims in the future, should that become necessary.

CONCLUSION

Applicants respectfully submit that the instant application is in condition for allowance. Entry of the amendments and an action passing this case to issue is therefore respectfully requested. In the event that another telephone conference would facilitate examination of this application in any way, the Examiner is invited to contact the undersigned at the number provided.

Respectfully submitted,

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